

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Patent of:	)	Group Art Unit: 1634
Kathryn Nance North	)	
	)	
Patent No. 7,615,342	)	
	)	Examiner: Steven C. Pohnert
	)	
Appl. No.: 10/527,831	)	Confirmation No.: 1014
	)	
Filed: 01/09/2006	)	
	)	
Atty. File No.: 5517-19	)	
	)	Electronically Filed
For: ACTN3 GENOTYPE	)	
SCREEN FOR ATHELETIC	)	
PERFORMANCE	)	

Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

STATEMENT UNDER 37 C.F.R. §1.705(b)(2)

Dear Sir:

1. This statement is respectfully submitted in support of the "Application for Patent Term Adjustment Including Request for Reconsideration Under 37 C.F.R. §1.705(d)" for the above-referenced patent. In view of the following, it is respectfully requested that Patentee be granted a patent term adjustment of **382** days.

2. The patent term adjustment indicated on published issued patent 7,615,342, issued November 10, 2009, under 35 U.S.C. §154(b) is 82 days (a copy of the first page of the patent is submitted herewith as Exhibit A). This determination of 82 days is in error. The correct patent term adjustment is **382 days**. The relevant ground for adjustment under 37 C.F.R. §1.702 is: (b) "Failure to issue a patent within three years

from the actual filing date of the application". The relevant dates and facts will be discussed below.

A. "Three Years Delay" Pursuant to 37 C.F.R. §1.703(b)

Patentees are entitled to a period of patent term adjustment pursuant to 37 C.F.R. §1.703(b). The period of delay under 37 C.F.R. §1.703(b) is equal to the number of days in the period beginning on the day after the date that is three years after the date on which the above referenced application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f), i.e, March 15, 2005, and ending on the date a patent is issued (hereinafter "Three Years Delay"). As the national phase commenced on March 15, 2005 and the patent issued on November 10, 2009, the period of Three Years Delay will be **605** days. This value was not listed in the calculations by the Office (See Exhibit B).

As set forth in 37 C.F.R. §1.703(f), Patentee is entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 C.F.R. §1.702 (hereinafter "Office Delay") reduced by the period of time during which Patentee failed to engage in reasonable efforts to conclude prosecution pursuant to 37 C.F.R. §1.704 (hereinafter "Applicant Delay"). With respect to the above-referenced application, the total period of Office Delay is the period of the Three Years Delay (**605** days) under 37 C.F.R. §1.703(b), as no other Office Delay under §1.703(a), (c), (d), or (e) is applicable.

To calculate the period of patent term adjustment, the total period of Office Delay is reduced by the period of Applicant Delay, which the USPTO calculates as a period of **223** days (see "Applicant Delay" in Exhibit B). Patentee does not dispute the Applicant Delay calculated by the Office. As detailed below, Patentee concludes that that Applicant Delay is **223** days. Accordingly, Patentee submits that the correct patent term adjustment for the above-referenced application is **382** days which is the

difference between the total period of Office Delay (**605** days) and the period of Applicant Delay (**223** days) (see below).

B. "Applicant Delay" Pursuant to 37 C.F.R. §1.704

Pursuant to 37 C.F.R. §1.704 the period of adjustment of the term of the patent due to examination delay is reduced by the period of Applicant Delay. The circumstances during the prosecution of the application that resulted in the above-identified patents are summarized as follows:

(i) Pursuant to 37 C.F.R. §1.704(b), the period of adjustment of the term of a patent under 37 C.F.R. § 1.703(a) through (e) is reduced by the period of time in excess of three months that is taken to reply to any notice or action by the Office. A non-final Office Action was mailed on May 8, 2007. Applicant responded to the non-final Office Action on November 8, 2007, which is three months and 92 days after the mailing date of the non-final Office Action. This constitutes a **92** day Applicant Delay under 37 C.F.R. § 1.704(b), in agreement with the Office.

(ii) A second non-final Office Action was mailed on February 4, 2008. Applicant responded to the second non-final Office Action on August 13, 2008 which is three months and 92 days after the mailing date of the second non-final Office Action. This constitutes a **92** day Applicant Delay under 37 C.F.R. § 1.704(b).

(iii) Pursuant to 37 C.F.R. §1.704(c)(8), the period of adjustment of the term of a patent under 37 C.F.R. § 1.703(a) through (e) is reduced by the submission of a supplementary reply or paper after a reply is filed. The period of adjustment is the number of days after the initial reply was filed. An Supplemental Reponse was filed on March 19, 2009, 36 days after the filing of the Amendment after Final Rejection on February 11, 2009. This constitutes a **36** day Applicant Delay under 37 C.F.R. §1.704(c)(8).

(iii) Pursuant to 37 C.F.R. § 1.704(c)(10), the period of adjustment of the term of a patent under 37 C.F.R. § 1.703(a) through (e) is reduced by the submission of an Amendment under § 1.312 after the issuance of a Notice of Allowance. The period of adjustment is the number of days beginning on the date the Amendment under § 1.312 was filed and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312. An Amendment under § 1.312 was filed on June 27, 2009 and the Office mailed a Response to Amendment, 2 days later, on June 29, 2009. This constitutes a **3 day Applicant Delay** under 37 C.F.R. § 1.704(c)(10).

The Total Applicant Delay is calculated as follows:

Response to First Office Action Delay	92 days
Response to Second Office Action Delay	92 days
Supplemental Response	36 days
Amendment under § 1.312	3 days
Total Applicant Delay	<b>223 days</b>

As indicated on the PTA History (Exhibit B), the Office has calculated a period of Applicant Delay of 223 days. This is in agreement with the Applicant Delay calculated by Patentee, as explained above.

C. Calculation of Correct Patent Term Adjustment Pursuant to 37 C.F.R. § 1.702(f)

As set forth in 37 C.F.R. § 1.703(f), Patentees are entitled to a period of patent term adjustment equal to the period of PTO Delay reduced by the period of Applicant Delay. Therefore, Patentee submits that the correct patent term adjustment for the above-referenced application is **382 days**, which is the difference between the total period of Office Delay (605 days) and the period of Applicant Delay (223 days).

D. No Terminal Disclaimer

In accordance with 37 C.F.R. § 1.705(b)(2)(iii), Patentee submits that the above identified application is not subject to a terminal disclaimer.

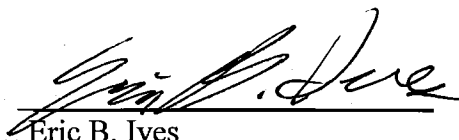
E. Conclusion

In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment and Certificate of Correction be issued to reflect a patent term adjustment of **382 days**.

Respectfully submitted,

SHERIDAN ROSS P.C.

By:



Eric B. Ives

Registration No. 50,928

1560 Broadway, Suite 1200

Denver, Colorado 80202-5141

(303) 863-9700

Date: 1-11-2010



US007615342B2

(12) **United States Patent**  
North(10) Patent No.: **US 7,615,342 B2**  
(45) Date of Patent: **Nov. 10, 2009**(54) **ACTN3 GENOTYPE SCREEN FOR ATHLETIC PERFORMANCE**

(75) Inventor: Kathryn Nance North, Glebe (AU)

(73) Assignee: Genetic Technologies Limited, Fitzroy (AU)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 82 days.

(21) Appl. No.: 10/527,831

(22) PCT Filed: Sep. 15, 2003

(86) PCT No.: PCT/AU03/01202

§ 371 (c)(1),  
(2), (4) Date: Jan. 9, 2006

(87) PCT Pub. No.: WO2004/024947

PCT Pub. Date: Mar. 25, 2004

(65) Prior Publication Data

US 2006/0121478 A1 Jun. 8, 2006

(30) Foreign Application Priority Data

Sep. 16, 2002 (AU) ..... 2002951411

(51) Int. Cl.  
C12Q 1/68 (2006.01)  
C07H 21/04 (2006.01)  
C12P 19/34 (2006.01)

(52) U.S. Cl. .... 435/6; 536/24.3; 435/91.2

(58) Field of Classification Search ..... 435/6;  
536/24.3

See application file for complete search history.

(56) References Cited

## U.S. PATENT DOCUMENTS

801,274 A	10/1903	Schulz
4,683,195 A	7/1987	Mullis et al.
4,683,202 A	7/1987	Mullis
4,800,139 A	1/1989	Mullis et al.
4,883,750 A	11/1989	Whiteley et al.
5,206,347 A	4/1993	Ruorakari et al.
5,279,721 A	1/1994	Schmid
5,919,626 A	7/1999	Shi et al.
5,952,174 A	9/1999	Nikiforov et al.

## FOREIGN PATENT DOCUMENTS

BP	0320308 B1	11/1993
EP	0329822 B1	6/1994
GB	2 202328 A	9/1988
WO	WO 88/10315	12/1988
WO	WO 89/06700	7/1989
WO	WO 89/09284	10/1989

## OTHER PUBLICATIONS

North et al, Nature Genetics (1999) vol. 21, pp. 353-354.\*

Lucia, et al International Journal of Sports Medicine (2006) vol. 27, pp. 880-894.\*

North Nature Genetics (1999) vol. 21 pp. 353-354.\*

Costill et al Journal of Applied Physiology (1976) vol. 40, pp. 140-153.\*

Rankinen et al, Medicine in sports and Exercise (2002) pp. 1219-2133.\*

Voet et al Biochemistry, published 199, p. 78.\*

Brenner et al (Trends in Genetics (2001) vol. 17, pp. 414-418).\*

O'Brien et al (Science magazine (1999) vol. 286, pp. 458-462, 479-481.\*

Pitiladis et al (Lancet (2003) vol. 366, pp. s16-s17).\*

Mills et al, Human Molecular Genetics (2001) vol. 10, pp. 1335-1346.\*

genecards.org/cgi-bin/carddisp.pl?gene=ACTN3&amp;search=actn3&amp;stuff=dat, pp. 1-11, Mar. 24, 2007.\*

Yang, et al, Med. Sci. Sport and Exercise (2005) vol. 37, s42.\*

Moran et al, European Journal of Human Genetics (2007) vol. 15, pp. 88-93.\*

Blanchard, Andrew, et al., "The Structure and function of  $\alpha$ -actinin," Journal of Muscle Research and Cell Motility 10, 280-289 (1989).Beggs, Alan H., et al., "Cloning and Characterization of Two Human Skeletal Muscle  $\alpha$ -Actinin Genes Located on Chromosomes 1 and 11" The Journal of Biological Chemistry, vol. 267, No. 13, Issue of May 5, pp. 9281-9288, 1992.Nave, Rudiger, et al., "Interaction of  $\alpha$ -actinin and nebulin in vitro," Elsevier Science Publishers, vol. 269, No. 1, 163-166, Aug. 1990.

Pap, Iris, et al., "Alpha actinin-CapZ, an anchoring complex for thin filaments in Z-line," Journal of Muscle Research and Cell Motility 20, pp. 187-197, 1999 Kluwer Academic Publishers.

Salnikow, Paula, et al., "Myotilin, a novel sarcomeric protein with two Ig-like domains, is encoded by a candidate gene for limb-girdle muscular dystrophy," Human Molecular Genetics, 1999, vol. 8, No. 7, pp. 1329-1336 1999 Oxford University Press.

Bellin, Robert M., et al., "Molecular characteristics and interactions of the Intermediate Filament Protein Synemin," The Journal of Biological Chemistry, vol. 274, No. 41, Issue of Oct. 9, pp. 29493-29499.

McGregor, Alistair, "Identification of the Vinculin-binding Site in the Cytoskeletal Protein  $\alpha$ -actinin" Biochem (1994) 301, pp. 223-233 (Printed in Great Britain).

(Continued)

Primary Examiner—Sarae Bausch

Assistant Examiner—Steven C Pohnert


(74) Attorney, Agent, or Firm—Sheridan Ross P.C.

(57) **ABSTRACT**

The present invention concerns novel methods of selecting or matching a sport or sporting event to an individual (e.g. a sprint/power sport or an endurance sport) and predicting athletic performance, the methods involving assessing ACTN3 genotype. In alternative embodiments, training regimens may be optimally designed for athletes by assessing the ACTN3 genotypes. Certain embodiments concern combining the assessment of the ACTN3 genotype with other known fitness-related genes to better assess the athletic potential of an individual. In addition, the genotypic analysis of the ACTN3 gene may be combined with physiological tests, physical measurements and/or psychological assessments to more optimally design a training regimen for an individual athlete.

14 Claims, 1 Drawing Sheet

## Exhibit 2

Patent Term Adjustment			
Filing or 371(c) Date:	01-09-2006	USPTO Delay (PTO) Delay (days):	305
Issue Date of Patent:	11-10-2009	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	223
Post-Issue Petitions (days):	+0	Total Patent Term Adjustment (days):	82
USPTO Adjustment (days):	+0	Explanation Of Calculations	

Patent Term Adjustment History			
Date	Contents Description	PTO(Days)	APPL(Days)
10-21-2009	PTA 36 Months	305	
11-10-2009	Patent Issue Date Used in PTA Calculation		
08-11-2009	Dispatch to FDC	↑	
07-29-2009	Mail Response to 312 Amendment (PTO-271)	↑	
07-27-2009	Response to Amendment under Rule 312	↑	
07-27-2009	Amendment after Notice of Allowance (Rule 312)		3
07-20-2009	Application Is Considered Ready for Issue		
07-16-2009	Issue Fee Payment Verified		
07-16-2009	Issue Fee Payment Received		
05-27-2009	TC Return to Pubs		
05-27-2009	Mail PUB other miscellaneous communication to applicant		
05-26-2009	PUB Other miscellaneous communication to applicant		
05-05-2009	Sequence Forwarded to Pubs on Tape		
04-17-2009	Mail Notice of Allowance		
04-08-2009	Document Verification		
04-08-2009	Notice of Allowance Data Verification Completed		
03-30-2009	Examiner's Amendment Communication		
03-24-2009	Examiner Interview Summary Record (PTOL - 413)		
03-24-2009	Date Forwarded to Examiner		
03-19-2009	Supplemental Response		36
02-16-2009	Miscellaneous Incoming Letter		↑
03-10-2009	Mail Examiner Interview Summary (PTOL - 413)		↑
03-02-2009	Examiner Interview Summary Record (PTOL - 413)		↑
02-19-2009	Date Forwarded to Examiner		↑
02-11-2009	Amendment after Final Rejection		↑
02-10-2009	Mail Examiner Interview Summary (PTOL - 413)		
02-04-2009	Examiner Interview Summary Record (PTOL - 413)		
02-03-2009	Change In Power of Attorney (May Include Associate POA)		

U.S. Serial No. 10/049,427  
Group Art Unit 1617

02-02-2009	Correspondence Address Change		
12-01-2008	Electronic Review		
11-28-2008	Email Notification		
11-28-2008	Mail Final Rejection (PTOL - 326)		
11-19-2008	Final Rejection		
08-13-2008	Information Disclosure Statement considered		
11-13-2008	Email Notification		
11-13-2008	Change in Power of Attorney (May Include Associate POA)		
11-03-2008	Correspondence Address Change		
09-19-2008	Date Forwarded to Examiner		
08-13-2008	Response after Non-Final Action		92
08-13-2008	Request for Extension of Time - Granted		↑
08-13-2008	Information Disclosure Statement (IDS) Filed		↑
08-13-2008	Information Disclosure Statement (IDS) Filed		↑
02-13-2008	Mail Non-Final Rejection		↑
02-04-2008	Non-Final Rejection		
11-08-2007	Information Disclosure Statement considered		
11-08-2007	New or Additional Drawing Filed		
11-27-2007	Date Forwarded to Examiner		
11-08-2007	Response after Non-Final Action		92
11-08-2007	Request for Extension of Time - Granted		↑
11-08-2007	Information Disclosure Statement (IDS) Filed		↑
11-08-2007	Information Disclosure Statement (IDS) Filed		↑
05-08-2007	Mail Non-Final Rejection		↑
03-29-2007	Non-Final Rejection		
03-02-2006	Information Disclosure Statement considered		
01-09-2007	Information Disclosure Statement considered		
02-18-2007	Date Forwarded to Examiner		
02-12-2007	Response to Election / Restriction Filed		
01-09-2007	Electronic Information Disclosure Statement		
01-09-2007	Information Disclosure Statement (IDS) Filed		
01-11-2007	Mail Restriction Requirement		
01-08-2007	Requirement for Restriction / Election		
09-19-2006	Case Docketed to Examiner in GAU		
04-22-2006	IFW TSS Processing by Tech Center Complete		
03-09-2006	Cleared by OIPE CSR		
03-09-2006	Cleared by OIPE CSR		
03-09-2006	Cleared by OIPE CSR		
03-09-2006	Cleared by OIPE CSR		



U.S. Serial No. 10/049,427  
Group Art Unit 1617

03-09-2006	Cleared by OIPE-CSR		
03-02-2006	Information Disclosure Statement (IDS) Filed		
03-02-2006	Information Disclosure Statement (IDS) Filed		
01-09-2006	371 Completion Date		
02-27-2006	Application Dispatched from OIPE		
02-27-2006	Notice of DO/EO Acceptance Mailed		
01-09-2006	Additional Application Filing Fees		
01-09-2006	Information Disclosure Statements		
01-09-2006	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applicant		